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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,074	07/08/2005	Darrell Sleep	11055.204-US	7594

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NOVOZYMES NORTH AMERICA, INC.  
500 FIFTH AVENUE  
SUITE 1600  
NEW YORK, NY 10110

EXAMINER
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GUDIBANDE, SATYANARAYAN R

ART UNIT	PAPER NUMBER
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1654

NOTIFICATION DATE	DELIVERY MODE
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09/03/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,074	<b>Applicant(s)</b> SLEEP, DARRELL	
	<b>Examiner</b> SATYANARAYANA R. GUDIBANDE	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-58 and 64-82 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12-19 and 24-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 20-23, 57, 58 and 64-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/20/09, 8/6/09</u>   | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of SEQ ID NO: 28 as the species and election of group I invention in the reply filed on 2/22/07 is acknowledged. The traversal arguments were addressed in the office action dated 4/19/07.

In the remarks filed on 5/21/09 applicants indicate that the prior pending sequence listing was incorrect with respect to SEQ ID NO: 28 and a new sequence listing has been filed incorporating the corrected sequence SEQ ID NO: 28.

The elected species SEQ ID NO: 28 (the corrected sequence) is not free of art. Prior found has been used in the rejections set forth below.

Claims 1-58 and 64-82 are pending.

Claims 9, 12-19 and 24-56 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/22/07.

Claims 64-82 have been added as new claims.

Claims 1-8, 10, 11, 20-23 and 64-82 are examined on the merit.

Any rejections and/or objections made in the previous office action dated 11/25/08 and not specifically mentioned here are considered as withdrawn.

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***New grounds of Rejections***

***Claim Objections***

Claims 11 and 58 are objected to because of the following informalities: Claims 11 and 58 recite peptide sequences that require SEQ ID NOs. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10, 11, 20-23, 57, 64-73 and 76-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant application, applicants claim a polypeptide comprising (i) a leader sequence, the leader sequence comprising: (a) an albumin secretion pre sequence having at least 60% sequence identity to SEQ ID NO: 28, and (b) the following motif: -X1-X2-X3-X4-X5- where X1 is phenylalanine, tryptophan, or tyrosine, X2 is isoleucine, leucine, valine, alanine or methionine, X3 is leucine, valine, alanine or methionine, X4 is serine or threonine and X5 is isoleucine, valine, alanine or methionine ; and (ii) a mature desired protein.

The SEQ ID NO: 28 is MKWVFIVSI LFLFSSAYS is an 18-mer sequence. A 60% identity to the above sequence having 10 amino acids identical to the SEQ ID NO: 28. However, the claim as recited does not recite whether the 10 amino acid residues that correspond to the 60% identity is 'contiguous' or the amino acid residues are present in a 'random manner'. If present as a contiguous sequence, then, whether it is the contiguous residues from the N-terminus

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or C-terminus or the positions of the amino acids if it is from other region other than the N- or C-terminus. If the 10 amino acids residues that corresponds to the SEQ ID NO: 28 is present in a random order then the claim as recited encompasses innumerable number of peptides. Hence the claim as recited with at least 60% identity to SEQ ID NO: 28 is indefinite and vague.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claims 1-8, 10, 11, 20-23, 57, 58 and 64-82 rejected under 35 U.S.C. 102(e) as being anticipated by Hauser (US 2006/0241027).

In the instant application, applicants claim a polypeptide comprising (i) a leader sequence, the leader sequence comprising (a) an albumin secretion pre sequence having at least 60% sequence identity to SEQ ID NO: 28, and (b) the following motif: -X1-X2-X3-X4-X5-

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where XI is phenylalanine, tryptophan, or tyrosine, X2 is isoleucine, leucine, valine, alanine or methionine, X3 is leucine, valine, alanine or methionine, X4 is serine or threonine and X5 is isoleucine, valine, alanine or methionine; and (ii) a mature desired protein.

Claim as recited implies that the instant polypeptide comprises: i) a leader sequence that comprises an albumin secretion pre sequence having at least 60% sequence identity to SEQ ID NO: 28, ii) a peptide motif -X1-X2-X3-X4-X5- wherein the variables are defined as shown above and iii) a mature protein.

Hauser discloses the following polypeptide sequence (Figure 2, SEQ ID NO 37)

**MKWV****FIVSILFL****FSSAYSRS** LDKRWQEWKITALLEQAQ IQQEKNEYELQKLDKWASLW  
EWFGGSGGSGGSGGSGGDAH KSEVAHRFKDLGEENFKALV LIAFAQYLQQCPFEDHVKLV  
NEVTEFAKTCVADESAENCD KSLHTLFGDKLCTVATLRET YGEMADCCAKQEPERNECFL  
QHKDDNPNLPRLVRPEVDVM CTAHFDNEETFLKKYLYEIA RRHPYFYAPELLFFAKRYKA  
AFTECCQAADKAACLLPKLD ELRDEGKASSAKQRLKCASL QKFGERAFAKAWAVARLSQRF  
PKAEFAEVSKLVTDLTQVHT ECCHGDLLECADDRADLAKY ICENQDSISSKLKECCEKPL  
LEKSHCIAEVENDEMPADLP SLAADFVESKDVCKNYAEAK DVFLGMFLYEYARRHPDYSV  
VLLRLAKTYETTLEKCCAA ADPHECYAKVFDEFKPLVEE PQNLIKQNCLEFEQLGEYKF  
QNALLVRYTKKVPQVSTPTL VEVSRNLGKVGSKCKHPEA KRMPCAEDYLSVVLNQLCVL  
HEKTPVSDRVTKCCTESLVN RRPCFSALEVDETYVPKEFN AETFTFHADICTLSEKERQI  
KKQTALVELVKHKPKATKEQ LKAVMDDFAAFVEKCKADD KETCFAEEGKKLVAASQAAL GL

The above disclosed polypeptide by Hauser comprises of peptide

**MKWV****FIVSIL****FSSAYS** that reads on the SEQ ID NO: 28 of the instant application and the sequence **FIVSI** corresponds to the motif -X1-X2-X3-X4-X5- wherein X1= Phe (F), X2 = Ile (I), X3= Val (V), X4= Ser (S) and X5 =Ile (I) hence reads on instant claims 1- 8, 11, 57, 58, 64-71, 74-82. The polypeptide of Hauser is a albumin-fusion protein and hence it is a non-naturally

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occurring protein which is also a mature protein. This reads on instant claim 72 that recites heterologous. The polypeptide **MKWVFIVSILFLFSSAYS** which corresponds to instant SEQ ID NO: 28 is part of the leader sequence which is fused at its N-terminal end of the desired protein by its C-terminal amino acid and hence reads on the instant claim 20. Hauser also discloses that the albumin fusion protein of the invention comprises at least a fragment or variant of a human serum albumin [0067] and hence reads on the instant claims 22 and 23. Hauser also discloses that invention is directed to proteins containing polypeptides at least 60-99% identical to a reference polypeptide sequence, e.g., a albumin fusion protein of the invention [0112]. This further reads on the instant claims 1, 22, 66-71 and 76-81.

### ***Conclusion***

Applicant's amendment to claims necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/  
Examiner, Art Unit 1654

/Andrew D Kosar/  
Primary Examiner, Art Unit 1654